510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.93

Submitter	The Anspach Effort 4500 Riverside Drive Palm Beach Gardens, FL 33410
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Date Prepared	January 12, 2007
Regulatory Name	Surgical instrument motors and accessories/attachments
Classification Name	Pump, Infusion
Product Code	HWE
Device Classification	Class I General, Restorative and Neurological Devices 21 CFR § 878.4820
Predicate Devices	Surgical Irrigation System -> K030576
Performance Standards	There are no known standards established specifically for an Irrigation System at this time. However, in addition to The 1995 "Draft 510(k) Checklist for Urological Irrigation System and Tubing Set" used in preparation of this Pre-Market Notification. The following standards are applicable to materials and components of the Anspach surgical irrigation system: 1. ASTM and other similar recognized material composition-related standards 2. IEC 60601 and other similar recognized electrical safety standards

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3. Quality System(s) in addition to US Federal requirements: ISO9001, ISO13485.
4. Bio-safety - Cytotoxicity ISO10993-5 (EN 30993-5) - Pre-sterilized devices only
5. ANSI/AAMI/ISO 11737-1:1995 Bio burden - Pre-sterilized devices only
6. ANSI/AAMI/ISO 11137:1994 - Pre-sterilized devices only
7. AMMI TIR 27: 2001 Alternative (11137) - Pre-sterilized devices only

Note: This list may not represent all applicable standards routinely used or used specifically for surgical irrigation systems.

Device Description

The Anspach Irrigation Pump System is a stand-alone pump and pump control system, designed to deliver a constant flow of irrigation fluid by means of a peristaltic pump.
The Irrigation Tube, (the subject of this submission), is a fluid delivery device that functions as a component of the irrigation system, to draw fluid from a standard IV bag to a 1/16" OD accessory for delivery to the operating site. Tubing size determines the available flow range for the system, while the pump RPM determines the specific flow rate within that range.

Indications for Use

Anspach Surgical Irrigation Systems are indicated for use with Anspach Surgical Motor Systems for providing controlled, cooling irrigation during cutting, shaping and removal of bone, including bones of the skull and spine.

Technological Characteristics

The Irrigation Tube has the same technological characteristics as the currently available irrigation tube. The only modification is solely in the inner and outer diameter and the length of the tube.
The Irrigation Tube is a component of the Surgical Irrigation System which is a delivery system of irrigation fluids available to the surgeon.

Conclusion

The irrigation tube, (component to the Surgical Irrigation System), and the subject of this submission, is substantially equivalent to the legally marketed irrigation tube component.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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The Anspach Effort, Inc.
% Mr. Jim Banic
Senior Regulatory Affairs Specialist
4500 Riverside Drive
Palm Beach Gardens, Florida 33410

Re: K063688
Trade/Device Name: Surgical Irrigation System
Regulation Number: 21 CFR 878.4820
Regulation Name: Surgical instrument motors and accessories/attachments
Regulatory Class: I
Product Code: HWE
Dated: December 7, 2006
Received: December 20, 2006

Dear Mr. Banic:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K063688

Indications for Use

510(k) Number (if known): K063688

Device Name: Surgical Irrigation System

Indications for Use:

Anspach Surgical Irrigation Systems are indicated for use with Anspach Surgical Motor Systems for providing controlled, cooling irrigation during cutting, shaping and removal of bone, including bones of the skull and spine.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063688